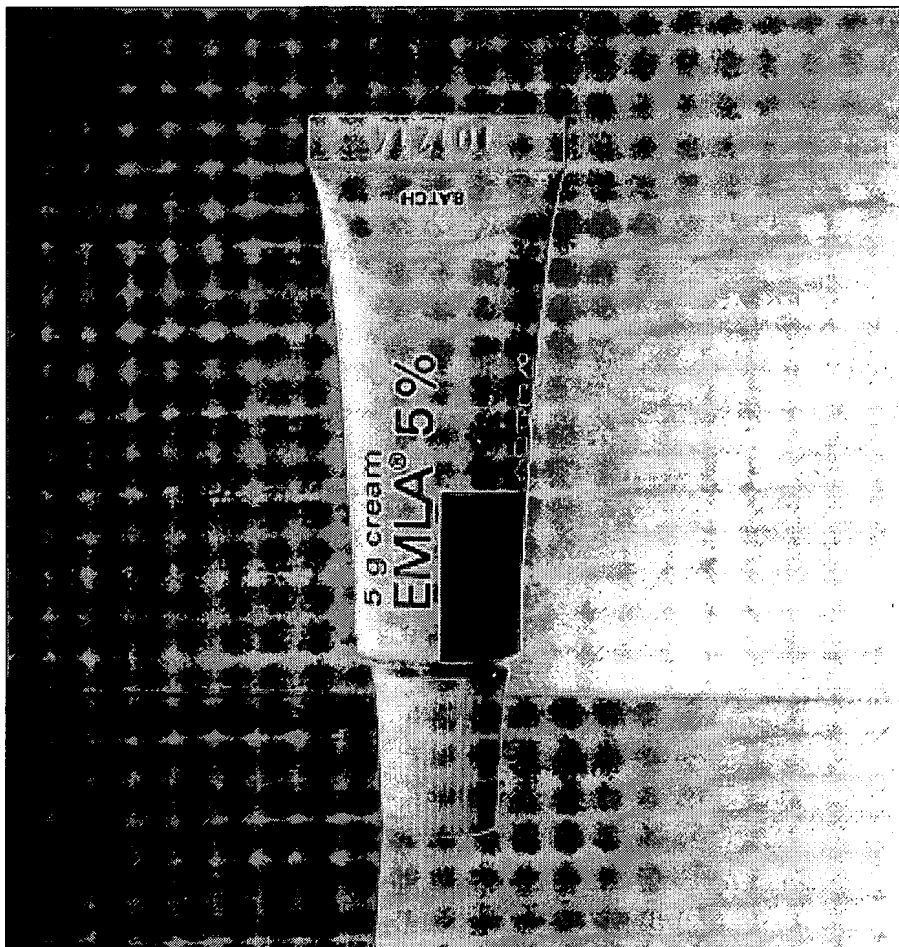


Directions For Use

Section 6

EMLA® CREAM



Presentation

EMLA cream is an oil-in-water emulsion system in which the oil phase consists of a eutectic mixture of lidocaine and prilocaine in a 1:1 ratio. One gram of EMLA cream contains lidocaine 25 mg and prilocaine 25 mg.

Recommended dosage and administration

Surface	Procedure	Application of EMLA Cream
Skin		
		Apply a thick layer of cream to the skin, approx 1.5 g/10 cm ² under an occlusive dressing.
Adults	Minor procedures, eg. needle insertion and surgical treatment of localised lesions	Approx. half a tube (2 g) cream for a minimum of 1 hour and a maximum of 5 hours.
	Dermal procedures on larger areas, eg. split-skin grafting	Approx. 1.5–2 g/10 cm ² for a minimum of 2 hours, and a maximum of 5 hours ⁽¹⁾ .
	Debridement of leg ulcers	Approx. 1.5 g/10 cm ² under occlusive dressing, 30–60 minutes. Maximum dose 10 g.
Children	Minor procedures, eg. needle insertion and surgical treatment of localised lesions.	Approx. 1 g/10cm ² Application time approx. 1 hour.
		Up to 20 g and 200 cm ² . Up to 10 g and 100 cm ² . Up to 2 g and 20 cm ² . Up to 1 g and 10 cm ² .
Genital mucosa Adults	Surgical treatment of localised lesions, e.g. removal of genital warts (condylomata acuminata)	Apply approx. 5–10 g EMLA for 5–10 minutes. No occlusive dressing is required. Commence procedure immediately thereafter.
Leg ulcers Adults	Mechanical cleansing/debridement of leg ulcer (s)	Apply a thick layer of cream, approx. 1–5 g/10 cm ² up to a total of 10 g to the leg ulcer(s). Cover with an occlusive dressing for at least 30 minutes to a maximum of 60 minutes. Cleansing of the ulcer should begin immediately on removal of the cream.

- (1) After a longer application time the anaesthesia decreases.
 (2) See also 4.4 'Special precautions for use' p.37.
 (3) Contact your local AstraZeneca representative for status of approval in children < 3 months of age in your country.


The recommended application time varies depending on the indication and the skin area to be anaesthetised, but usually ranges between 60 and 120 minutes on intact skin. Two hours after the actual application the maximum anaesthesia is achieved and the anaesthetic effect lasts for several hours.

Delicate skin, e.g. around the eyes, on the lips or on the genital skin of the male, has a more rapid uptake and anaesthetic response.


On genital mucosa the recommended application time is 5–10 minutes. The duration of the anaesthesia is shorter, approximately 10–20 minutes.

In the treatment of leg ulcers it is recommended that cream is applied for at least 30 minutes prior to treatment and for a maximum of 60 minutes. Cleansing of the ulcers should begin without delay on removal of the cream.


Instructions for use




(A). Make sure that the area of skin to be treated is clean and dry. Apply a thick layer of cream (1.5–2 g /10 cm²).



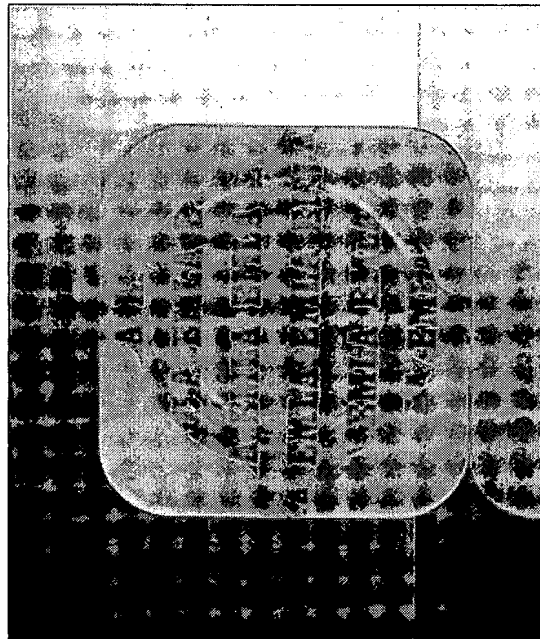
(B). Peel the paper lining from the occlusive dressing and cover the cream (unless treating genital mucosa). When treating large areas with cream, the area can be wrapped in plastic cling film.



(C). Smooth down the edges of the dressing securely and then remove the paper frame.



(D). Record the time of application on the dressing. After the correct application time, remove the cream and clean the entire area. For leg ulcer and genital mucosal procedures, treatment should commence immediately after the removal of the cream.



Presentation

EMLA patch is a unit-dose formulation of EMLA in the form of a dressing with built-in occlusion. One EMLA patch consists of an absorbent cellulose disc which is saturated with 1 g of EMLA emulsion 5% (active ingredients: lidocaine 25 mg and prilocaine 25 mg) and affixed to a patch system of laminate backing and adhesive tape frame. The contact surface area of the EMLA-saturated disc is approximately 10 cm².

EMLA patch is suitable for use in the provision of dermal anaesthesia prior to all needle insertions and for minor superficial skin surgery on localised lesions.

The EMLA patch offers certain advantages:

- the product simplifies application of EMLA as it requires minimal patient and staff instruction
- it is self-occlusive
- it delivers a precise dose per application, minimising the likelihood of over- or underdosing
- it simplifies home application of EMLA and, where available over the counter, it enables the patient to easily apply EMLA before visiting the doctor.

Recommended dosage and administration

Surface	Procedure	Application of EMLA Patch
<i>Skin</i>		1 patch anaesthetises an area of 10 cm ² .
Adults and children aged > 1 year (1)	Minor procedures, eg, needle insertion and surgical treatment of localised lesions:	Apply EMLA patch to the selected skin area. Minimum application time 1 hour.
Infants 3–11 months (2)		Application time: approx. 1 hour. Based on clinical data for EMLA cream, not more than two EMLA patches should be applied at the same time in infants aged 3–12 months.
Neonates 0–2 months		The approximate application time is 1 hour. A longer application time has not been documented in neonates. Not more than one EMLA patch should be applied at the same time (3).

- (1) For children over one year old, please refer to the dosing recommendations for EMLA cream.
- (2) See also 4.4 "Special precautions for use" p. 37.
- (3) The size of the patch makes it less suitable for use on certain parts of the body of neonates and infants.

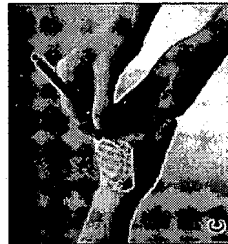
Instructions for use



(A). Make sure that the area is clean and dry. Take hold of the aluminium flap of the patch and bend it back. Hold the corner of the skin-coloured patch layer and pull the two layers apart to separate the adhesive surface from the aluminium paper backing. Do not touch the white round pad, which contains EMLA.



(B). Place the white round pad over the area to be treated. Press firmly around the edges only of the patch to ensure good adhesion to the skin. Do not press the centre during application as emulsion might squeeze out under the adhesive.



(C). Record the time of application on the dressing. After the correct application time, remove the patch and clean the skin.

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